CAMPBELL UNIVERSITY	**IRB Guidance:** Investigator Research Protocol

The purpose of the Investigator Research Protocol is to describe the proposed research in sufficient detail for investigators, research staff and institutional committees understand the purpose and research activities being conducted in sufficient detail. This allows the IRB to determine if approval criteria for human subjects research is met as defined in the federal regulations. An Investigator Research Protocol is not required if research is sponsored and the sponsor has provided an Investigator Protocol.

The Investigator Protocol is a narrative of the study and is a living document to be maintained over the life of the protocol. An Investigator Research Protocol is required for every protocol submitted for IRB review.

The following guidelines are designed to help researchers develop a comprehensive yet succinct Investigator Research Protocol for inclusion with your Initial/New Protocol Submission. This guidance document covers the following:

I. General Considerations

- This guidance is comprehensive to include aspects of research from varying disciplines. Do not overwhelmed by the length of this guidance document.
- Not all points will apply to all research.
- For each section, this guidance includes a description of why the information is important for IRB review (in italics).
- The Investigator Research Protocol must be submitted with the initial/new submission and continuing review submission, if CR is required.
- The Investigator Research Protocol will need to be updated via an Amendment Submission to reflect any proposed changes and submitted with all other applicable protocol materials.
- There is no minimum or maximum length required.
- A list of commonly used human subjects definitions can be found in the SOP section of the CU IRB website.

II. Instructions

- The Investigator Research Protocol must provide sufficient detail for you to complete the Initial/New Submission Form and for IRB reviewers to be able to understand and evaluate the research protocol.
- The focus of the Investigator Research Protocol must be written in such a way as to be understood by readers outside of the research field of expertise. Explain discipline specific terms, procedures and concepts.
- The version date must be updated each time this Investigator Research Protocol is revised whether or not the revisions are being requested by the IRB during the review process or being proposed by the investigator though the submission of an Amendment.

III. Investigator Research Protocol Content

- When drafting the Investigator Research Protocol, follow the format and use the section headings (i.e. A – I) provided below, refer to the bulleted items for section content.
- For each section, this guidance includes a description of why the information is important for IRB review (*in italics*).

A. Introduction and Background

In reviewing the protocol, the IRB must consider the rationale for the project and the importance of the knowledge that may reasonably be expected to result.

- **Briefly** summarize the nature, scientific or scholarly rationale and significance of the proposed study and any relevant background information on the topic. Explain the relevance of the project to previous and/or continuing work in the field. Discuss why novel inquiry is necessary. If there is a gap in knowledge, explain how it is anticipated that this research will address the gap. If this research is intended to replicate previous research, provide rationale. Provide citations appropriately.

B. Purpose/Specific Aims/Project Objectives

The IRB must evaluate the objective of the research in order to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.

- **Clearly** outline the specific research question(s). Include the study objective(s) and/or hypothesis.

C. Methods, Materials, and Analysis

The project design, methods and procedures must be adequately described, in order for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine/standard care/practice or evaluation.

NOTE: The focus of this section is on methods and procedures. Risks must be discussed later in Section G.

- Describe the project design and research methods used to meet the project aims and objectives stated above (e.g., on-line survey, open ended interview, randomized controlled trial, participant observation, field based research, lab/task based, etc.).
- If there will be multiple groups of participants completing different sets of activities/tasks, clearly delineate the activities to occur for each group.
- Describe in chronological order all research activities/procedures involving participants. This should walk the reader step-by-step through the research activities and include a description of the research procedures and instruments.
    - Include the title and descriptions of any measures, questionnaires, tasks, tests, and/or procedures. Titles need to be used consistently throughout the description(s).
    - The description must include whether these are standardized in the field or designed for this specific study.
    - Depending on the complexity or number of procedures, consider inserting a table or attaching an inventory list of measures or questionnaires as an appendix.
    - If the research involves any procedures typically used in a biomedical/clinical setting and/or administration of medications (e.g., blood draw, ultrasound, MRI, x-rays/radiographs, etc.) include the following:
        - The justification for the use of the procedures.
        - The dosage.
        - The qualifications of project personnel to conduct the procedures.
    - If using deception, discuss the related activities, what that deception entails, and when and how the debriefing process will occur.
- Include an estimate of the time each participant will spend completing the activities (in minutes or hours), the number of sessions the participant will engage in, and the total length of participation (in days, weeks, months, or years) from the beginning to the end of the project.
- If follow-up with participants is planned, discuss the procedures and under what circumstances follow-up will occur.

- Describe the methods of data collection and recording that will be utilized in the project (i.e., hand-written notes, survey platform, computer programs, videotapes, audiotapes, photographs, etc.)
- Describe the specific locations where the activities will be conducted (i.e, in what labs, clinics, field sites, or online platforms will the procedures occur?). The investigator must determine if additional local, State and/or international policies and regulations are applicable to the research and include this information in the Research Plan.
- Explain how the data will be analyzed/studied (i.e., quantitatively or qualitatively and what statistical test are planned), how the interpretation will address the research questions, and how the research will be disseminated.
    - Describe how the data will be reported (e.g., aggregated, anonymously, pseudonyms for participants, etc.)

D. Research Population, Recruitment Methods, and Compensation

In order to approve research, the IRB must determine that the selection of participants is equitable and reasonably related to the purpose and aims of the research. The IRB must also consider whether adequate safeguards are in place to minimize any risks that are unique to vulnerable populations (e.g., fetuses, children, prisoners, cognitively impaired persons, etc.). To make this determination, the IRB must review all methods and materials used to contact and recruit potential participants, including letters, flyers, emails, etc.

1. Participant Population

- Describe the participant population:
    - Provide the rationale for including the participant population. When including any vulnerable populations in the project (e.g., children, cognitively impaired persons, etc.) explain why inclusion of this population is necessary to accomplish the research aims.
    - List the inclusion criteria such as age range, race or ethnicity, gender, language and condition, etc.)
    - List the exclusion criteria and rationale.
    - Discuss how individuals will be screened for eligibility.
    - Address whether or not participants are fluent in English and/or if any of the project activities (i.e. recruitment, consent, assessments, etc.) will be carried out in a language other than English.
        - Describe how the research team member(s) are fluent in the language of the participants or if a translator will be used.
        - Describe how materials will be presented in the language understandable to participants (e.g. will translated materials be

used?). If there is not written language, state this and explain translation.

- Discuss the number of participants needed for the project including the following:
    - Provide the targeted number of individuals to be included in the research. If more than one groups, provide numbers needed for each group and total number for the entire project. Ranges are acceptable (i.e. 20-25 individuals, survey distributed to 200 people and expected 65% response rate).
    - Provide rationale for targeted numbers (e.g. power analysis, etc.).

2. Recruitment Methods

- Describe the process and/or method by which participants will be recruited for the research, including the following:
    - When and how will each step of recruitment occur (i.e., initial contact, introductions, follow-ups, etc.)?
    - Describe how the participant population is accessed. Discuss relevant permissions (e.g., access to listservs, online databases, access to HIPAA or FERPA covered information, etc.)
    - State any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts. If there are no written recruitment materials, explain.
    - Explain which research roles (e.g., PI, Research Assistant, Student, etc.) will recruit participants and how they will be trained.
    - Describe any screening tests and or procedures that will be used to ensure that potential participants are eligible to participate.
    - If any part of the recruitment procedures involves a language other than English describe any differences in the recruitment procedures for non-English speaking participants.
- For research involving treatment (e.g., behavioral intervention, drug or device projects, etc.):
    - Describe how research treatment will be distinguished from regular treatment.
    - Indicate whether the individuals who will recruit participants have provided or will provide treatment or care to the prospective participants. If treatment providers also have a role in the research, describe measures to avoid or diminish undue influence.

3. Compensation/Reimbursement

- If there is the possibility that there will be costs to the participant or to a third party (e.g., an insurer), identify the specific expenses (e.g., drug tests, procedures, hospitalization, travel, etc.) and provide a justification for those costs.

- If participants are to receive compensation for their time, please describe the following or simply state no compensation will be offered:
    - The amount and nature of the compensation (e.g., cash, gift card, course credit, etc.).
    - Explain how an when compensation will be provided, including payment schedules, whether or not compensation will be reduced if the participant does not complete all activities in the project, and how any proration will occur.
    - Explain how the methods and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of project visits, travel expenses, age of participant population, etc.).

4. Withdrawal of Participants

- Describe any anticipated circumstances under which participants will be withdrawn from the research without their consent.
- Explain any procedures for orderly termination.
- Explain procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.
- Describe what will happen to participant's data is they are withdrawn from the project.

E. Informed Consent Process

Informed consent is a process not just a form, and obtaining informed consent is a central protection for human participants. The IRB must ensure the informed consent process clearly discloses and facilitates the understanding of all information needed to make an informed decision to participate while promoting the voluntariness of participation.

Below are the key component of the informed consent process. In some cases it may be appropriate to see a waiver or alteration of informed consent or a waiver of documentation of informed consent from the IRB.

1. Informed Consent Process

- Describe the informed consent process, including:
    - How the required elements of informed consent will be conveyed to participants (i.e., informed consent documents, verbal script, online statement, letter, etc.).
    - Where and when the informed consent process will take place (i.e., in-person in private room, phone, etc.).

  - Any waiting period available between informing the prospective participant and obtaining the consent.
  - Any cultural considerations (e.g., tribal or group permission requirements, age of majority, technological limitations, etc.)
  - Steps that will be taken to ensure voluntary participation and to minimize the possibility of coercion or undue influence.
  - Which research roles (e.g., PI, Research Assistant, student, etc.) will conduct the consent process and how that person will be trained (e.g., previous experience or related training, on-on-one training with PI, etc.).
  - If multiple participant groups or consent procedures are to be included, these need to be clearly delineated.
- In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent. See ***IRB SOP: Waiver or Alteration of the Informed Consent Process*** for the criteria that must be met and information that must be included in this section to request consideration of waiver or alteration of informed consent by the IRB.

2. Facilitate Understanding

- Describe how the investigator will ensure that the participants understand all aspects of their involvement in the research (i.e., will participants be asked questions about the procedures, or encouraged to ask questions?).
- Describe any special provisions for individuals who might have trouble comprehending the consent information.
- If any participants do not speak English, describe:
  - Whether or not the researcher is fluent in the language.
  - Whether or not and how a translator will be used.
  - Whether or not translated consent materials will be used.
  - Whether or not there are any differences in the consent process for different populations based on the language they speak.
- Describe the process by which the investigator will ensure ongoing consent.

3. Documentation

- Describe how the researcher plans to document that each participant has provided informed consent and/or assent.
- In certain circumstances, the IRB may waive the requirement to obtain a signed consent form based on specific criteria. See ***IRB SOP: Waiver or Alteration of Documentation of Informed Consent*** for the criteria that must be met and information that must be included in this section to request consideration of a waiver of documentation from the IRB.

4. Additional Considerations

If the research involves:

- Minors (those under the age of majority) or individuals of diminished capacity:
  - Describe the capacity of the participant and their ability to assent.
  - Describe how assent to participate will be obtained and documented.
    - If a waiver of assent or waiver of assent documentation is being requested, provide justification.
  - Explain how the permission of the parent(s), guardian(s), or legally authorized representatives (LARs) will be obtained and documented.
    - If a waiver of permission or waiver of permission documentation is being requested, provide justification.
- Deception:
  - Explain how participants will be deceived and why it is necessary for the project.
  - Deception is an alteration of informed consent; provide justification for how the use of deception meets the criteria for alteration of informed consent. See *IRB SOP: Waiver or Alteration of the Informed Consent Process* and *IRB SOP: Waiver or Alteration of Documentation of Informed Consent*, for the criteria that must be met and information that must be included in this section to request consideration of a waiver of documentation from the IRB.
  - If deception is used in research involving **benign behavioral interventions** in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording and at least one of the following criteria is met:
    - The identity of the participants cannot readily be ascertained, directly or through identifiers linked to the participants, or
    - Disclosure of the participant's responses outside of research would not reasonably place the participants at risk of criminal or civil liability ore be damaging to the participants' financial standing, employability, educational advancement, or reputation, or
    - The identity of the participants can readily be ascertained and the IRB conducts a limited IRB review.
  - The participant must authorize the deception through a prospective agreement in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Prospective agreement does not require the use of an informed consent document.
  - Describe the debriefing process and provide script.

- **Protected Health Information and HIPAA:**

  HIPAA applies to Protected Health Information (PHI). PHI is individually identifiable health information that is created or maintained by a covered entity (health care providers, hospitals, physician offices, health care clearing houses, health care plans), or their business associate(s).)

  (If you research does not involve the use of medical record information maintained by a covered entity and if the information generated from research will not be placed into the medical record, then HIPAA does not apply.)

  - If the research involves the use of protected health information from a covered entity, describe how authorization from participants to access and use their information will be obtained (i.e. signed HIPAA authorization form, informed consent which includes HIPAA authorization).
    - If requesting a waiver of authorization, see *Request for HIPAA Alteration/Waiver of Individual Authorization* form for the criteria that must be met. Justification for how the criteria are satisfied must be included in this section.

F. Participant Privacy, Data Disposition, and Data Confidentiality

In order to approve research, the IRB must determine that there are adequate provision in place to protect the privacy of subjects and maintain the confidentiality of research records and data collected.

1. Privacy

- Describe the steps that will be taken to promote the protection of participants' privacy. Consider the following:
  - The methods used to identify and contact potential participants
  - The settings in which an individual will be interacting with an investigator.
  - The appropriateness of all personnel present for research activities.
  - The methods used to obtain information about participants.
  - The sensitivity of the requested information:
    - In relation to the potential privacy risks of the information.
    - In relation to options for participants to disclose identity.
  - Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
  - Steps to ensure access to the minimum amount of information necessary to complete the project.
    - Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory

definition of "human participant" (e.g., a participant provides information about a family member for a survey).

- Describe what personal or identifiable information will be obtained to facilitate the research and as part of data collection. If participant data will collected without identifiers, please state this.

2. Data Disposition

- Describe what data will be collected, including identifiable information and audio/video/digital recordings or photos. In addition, consider the following:
  - Any other information collected to facilitate the research (i.e., contact information for recruitment).
  - Any existing data and its disposition (i.e., obtaining data from another source coded, or identifiable, etc.).

3. Confidentiality

- Describe the steps that will be taken to secure data and/or specimens for the research.
- Describe if participants' private information will be coded (i.e., identifying information has been replaced with a number, pseudonym, etc.), include:
  - How the key to decipher the code (i.e., list linking participant's names with pseudonyms or participant number) will be stored?
  - Who will have access to the code key?
  - If, how, and why the code key will be retained.
- If participant identities will be disclosed as a result of this research (e.g., attributing a direct quote, etc.), provide:
  - Justification for appropriateness of direct identification
  - Parameters for disclosure (e.g., will participants be allowed to review prior to dissemination).
  - How permissions from participant will be solicited including restrictions.
- Describe storage and transfer including:
  - How the data will be collected and stored, including format, (e.g., audio/visual recordings or photographs, hard or electronic copy, identifiable or de-identified).
  - Security during transmission and sharing between researchers and participants.
  - Who will have access to data (e.g., training of staff, authorization of access)?
  - Who is responsible for receipt or transmission of the data or specimens?
  - How will data or specimens will be transported?
  - How long the records will be kept after the study is completed.
  - The security of the area where data will be stored (e.g., locked office, password protected computer, encryption, firewalls, virus detection, etc.).

- Describe any intent for future use of data beyond this research including:
  - If other researchers will be permitted access/use of the data.
  - How data will be maintained and stored.
  - How participant permissions for the future use will be obtained and tracked.
- If seeking a Certificate of Confidentiality through NIH, this needs to be stated.

4. Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants.

- Describe:
  - The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee (DSMC/DMC/IDMC) and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
  - The frequency of DSMB Meeting.
  - What data are reviewed, including safety data, untoward events, and efficacy data?
  - How the safety information will be collected. (e.g., with case report forms, at study visits, by telephone call with participants).
  - The frequency of data collection, including when safety data collection starts.
  - Who will review the data?
  - The frequency or periodicity of review of cumulative data.
  - The statistical tests for analyzing the safety data to determine whether harm is occurring.
  - Any conditions that trigger an immediate suspension of the research.

G. Participant Privacy, Data Disposition, and Data Confidentiality

In order to approve research, the IRB must determine that there are adequate provision in place to protect the privacy of subjects and maintain the confidentiality of research records and data collected.

1. Privacy

- Describe the steps that will be taken to promote the protection of participants' privacy. Consider the following:
  - The methods used to identify and contact potential participants
  - The settings in which an individual will be interacting with an investigator.
  - The appropriateness of all personnel present for research activities.
  - The methods used to obtain information about participants.

  - The sensitivity of the requested information:
    - In relation to the potential privacy risks of the information.
    - In relation to options for participants to disclose identity.
  - Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
  - Steps to ensure access to the minimum amount of information necessary to complete the project.
  - Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory definition of "human participant" (e.g., a participant provides information about a family member for a survey).
- Describe what personal or identifiable information will be obtained to facilitate the research and as part of data collection. If participant data will collected without identifiers, please state this.

2. Data Disposition

- Describe what data will be collected, including identifiable information and audio/video/digital recordings or photos. In addition, consider the following:
  - Any other information collected to facilitate the research (i.e., contact information for recruitment).
  - Any existing data and its disposition (i.e., obtaining data from another source coded, or identifiable, etc.).

3. Confidentiality

- Describe the steps that will be taken to secure data and/or specimens for the research.
- Describe if participants' private information will be coded (i.e., identifying information has been replaced with a number, pseudonym, etc.), include:
  - How the key to decipher the code (i.e., list linking participant's names with pseudonyms or participant number) will be stored?
  - Who will have access to the code key?
  - If, how, and why the code key will be retained.
- If participant identities will be disclosed as a result of this research (e.g., attributing a direct quote, etc.), provide:
  - Justification for appropriateness of direct identification
  - Parameters for disclosure (e.g., will participants be allowed to review prior to dissemination).
  - How permissions from participant will be solicited including restrictions.
- Describe storage and transfer including:
  - How the data will be collected and stored, including format, (e.g., audio/visual recordings or photographs, hard or electronic copy, identifiable or de-identified).

  - Security during transmission and sharing between researchers and participants.
  - Who will have access to data (e.g., training of staff, authorization of access)?
  - Who is responsible for receipt or transmission of the data or specimens?
  - How will data or specimens will be transported?
  - How long the records will be kept after the study is completed.
  - The security of the area where data will be stored (e.g., locked office, password protected computer, encryption, firewalls, virus detection, etc.).
- Describe any intent for future use of data beyond this research including:
  - If other researchers will be permitted access/use of the data.
  - How data will be maintained and stored.
  - How participant permissions for the future use will be obtained and tracked.
- If seeking a Certificate of Confidentiality through NIH, this needs to be stated.

4. Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants.

- Describe:
  - The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee (DSMC/DMC/IDMC) and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
  - The frequency of DSMB Meeting.
  - What data are reviewed, including safety data, untoward events, and efficacy data?
  - How the safety information will be collected. (e.g., with case report forms, at study visits, by telephone call with participants).
  - The frequency of data collection, including when safety data collection starts.
  - Who will review the data?
  - The frequency or periodicity of review of cumulative data.
  - The statistical tests for analyzing the safety data to determine whether harm is occurring.
  - Any conditions that trigger an immediate suspension of the research.

H. Potential Research Risks or Discomforts to Participants

In order to approve the research, the IRB must consider the risks posed to participants by the research and any efforts to mitigate those risks. The IRB needs to determine that the risks have been both minimized and are reasonable in relation to the anticipated

benefits to participants as well as to the importance of the knowledge that may be gained. The IRB will also consider whether the informed consent process provides potential participants with an accurate and fair description of the risks or discomforts.

- Describe any reasonably foreseeable risks of harm or discomforts for individuals and/or groups that may result from participation in the research. While risks associated with participation may not be expected, most protocols carry some risk. Consider the following:
  - Information risks (e.g., loss of privacy and/or breach of confidentiality).
  - Psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of part emotional experiences).
  - Social risks (e.g., social stigma, chance of being ostracized or shunned), economic risks (e.g., change in employment or insurability).
  - Physical risks or harms (e.g., fatigue, pain or discomfort, potential for injury, illness or disease, or death, side effects and contraindications of drugs or substances used in the research).
  - Legal risks (e.g., risk of prosecutions, mandatory reporting).
  - Genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.).
- For each identified risk, explain all of the following:
  - Likelihood of the risk occurring.
  - Magnitude of the effects the risk would have should they occur.
  - How the risk will be minimized.
  - How the risk will be disclosed in the informed consent process.
- If the protocol involves treatment or intervention, describe the "standard of care/practice" and escribe how the risks of the research activities or interventions compare.
- When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the participants.
  - If there is a separate Data and Safety Monitoring Plan (DSMP), state this and attach.
  - If there is an established Data and Safety Monitoring Board/Committee (DSMB/C) to monitor the progress of the research and the safety of participants, clearly indicate this. The frequency and operations of the DSMB/C should be covered in the DSMP.

I. Potential Benefits of the Research

In order to approve this research, the IRB must determine that the anticipated benefits to research participants and the knowledge researchers expect to gain are reasonable in relation to the potential risks.

- Describe any anticipated benefits that may result from the research. Consider the following:
    - Direct benefits that may result from participation (e.g., psychological or emotional benefits, learning benefits, physical benefits, diagnostic or therapeutic benefits, etc.). If there are no direct benefits to participants, clearly state this.
    - Benefits to the general participant population.
    - General benefits of the research for society, science and humanity; potential generalizable knowledge.

NOTE: Compensation for participant is not a benefit and should not be included in this section.

J. Investigator Qualifications, Roles and Training

In order to approve this research, the IRB needs to determine that research personnel are adequately trained and knowledgeable regarding the study procedures and the protection of human research participants.

1. Investigator Qualification

- Provide a brief description for all key research personnel (i.e., Principal Investigator, Faculty Advisor, Co-Investigators or any other research personnel with responsibility for study oversight and research design). Include all the following:
    - Academic background.
    - Research experience.
    - Experience with the proposed participant population.
    - Experience with the proposed procedures and methodology.
    - For students, include any applicable coursework (e.g., research methodology courses).

2. Roles and Research Duties

- Describe the roles and the associated research activities/duties. For example, Students will consent participants and administer surveys.
- Note: Do not list individual names. Limit roles to Principal Investigator, Co-Investigator, Faculty Advisor, Research Assistant, Project Coordinator, and Student.

3. Training and Oversight

- Describe how the project personnel will be adequately trained to conduct research activities in accordance with the approved protocol and in compliance with federal regulations and university policy.
- Describe any specific training or expertise required for procedures proposed in this research. Explain all the following:

- Training standards or requirements that must be met.
- Who will be providing the training?
- How will the training be tracked/documented?

4. **Translator**
   - If a translator will be used for any aspects of the research, provide the translator's name and qualification for translation (e.g., native speaker, student of the language, etc.)